In the United States Court of Federal Claims

RICHARD MUNOZ,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

No. 21-1369V
(Filed: December 20, 2024) [1]

Amber Diane Wilson, Wilson Science Law, Washington, DC, for Petitioner.

Naseem Kourosh, Civil Division, United States Department of Justice, Washington, DC, for Respondent.

OPINION AND ORDER

LERNER, *Judge*.

Petitioner Richard Munoz seeks review of Chief Special Master Brian H. Corcoran's Decision denying compensation for his claim under the National Vaccine Injury Compensation Program ("Vaccine Act"), 42 U.S.C. § 300aa *et seq*. Pet'r's Mot. for Review ("Mot.") at 1, ECF No. 73. Petitioner brought this action alleging that the tetanus, diphtheria, and pertussis ("Tdap") and pneumococcal vaccines caused him to develop polymyalgia rheumatica ("PMR"). *Id.* at 2. Chief Special Master Corcoran found that Petitioner failed to meet his burden to prove a medical theory causally connecting the vaccine to his injury as set out in the first prong of the *Althen* test. Entitlement Decision ("Dec.") at 17, ECF No. 70. *See also Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Petitioner alleges the Chief Special Master made legal errors and applied an impermissibly high evidentiary burden. Mot. at 1, 5. For the reasons below, this Court **DENIES** Petitioner's Motion for Review.

I. Background

A. Factual Background[2]

Petitioner Richard Munoz was sixty-five years old when he received the Tdap and pneumococcal vaccines on July 2, 2019, during his annual primary care physician ("PCP")

[1] This Opinion was initially filed on December 5, 2024. The parties were afforded fourteen days to propose redactions. The parties did not. Accordingly, the Court reissues this Opinion in its original form, with an update to the Vaccine Program's title in the first paragraph.

[2] To resolve the pending Motion for Review, the Court summarizes the facts as presented in the Chief Special Master's Decision.

visit. Dec. at 2. He was previously treated in 2016 for hip pain that was deemed "likely related to lower back dysfunction." *Id.* at 2 (citing Ex. 3 at 123, 139–40, ECF No. 6). In the months prior to his vaccination, Petitioner reported paresthesias[3] in his arm and right leg, joint pain in his right knee, and syncope.[4] *Id.* (citing Ex. 5 at 26, 36, ECF No. 6). An x-ray of his cervical spine from February 2019 showed "moderate cervical spondylosis"—a "degenerative joint disease affecting the cervical vertebrae . . . sometimes with pain or paresthesia radiating along the upper limbs as a result of pressure on the nerve roots." *Id.* at 2 (citing Ex. 5 at 34), 2 n.3. The same x-ray revealed radiculopathy[5] in the cervical spine. A May 2019 x-ray also identified evidence of osteoarthritis in his knee. *Id.* at 2; Ex. 5 at 62.

Three weeks after receiving the vaccines, Mr. Munoz returned to his PCP reporting "aching joint pain and constant fatigue." *Id.* (citing Ex. 5 at 18). He reported that these symptoms began approximately three days after his vaccination. *Id.* Petitioner continued to experience fatigue and joint pain in August 2019 and, by mid-August, additional hand swelling. *Id.* In September 2019, a rheumatologist indicated Mr. Munoz might have PMR.[6] *Id.* A neurologist proposed the possibility of vaccine-induced brachial neuritis, which was supported by some other physicians. *Id.* However, as Petitioner continued to seek treatment, "PMR continued to be the prevailing assessment for his condition" through 2020. *Id.* at 3. Petitioner's PMR diagnosis was not contested by the parties. *Id.* at 16; Mot. at 2; Resp't.'s Mem. in Resp. to Pet'r's Mot. for Review ("Resp.") at 1, ECF 77.

B. Procedural Background

On May 18, 2021, Mr. Munoz filed a petition in this Court alleging that the 2019 vaccinations caused his PMR. Pet., ECF No. 1. The parties submitted expert reports and

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[3] "Paresthesia refers to a burning, itching, tingling, or prickling sensation that is usually felt in the hands, arms, legs, or feet." *Glossary of Neurological Terms*, Nat'l. Inst. of Neurological Disorders & Stroke, https://www.ninds.nih.gov/health-information/disorders/glossary-neurological-terms (last visited Dec. 4, 2024).

[4] "Syncope is used to describe a loss of consciousness for a short period of time." *Syncope*, Nat'l Inst. of Neurological Disorders & Stroke, https://www.ninds.nih.gov/health-information/disorders/syncope (last visited Dec. 4, 2024).

[5] "Cervical radiculopathy occurs when a nerve in the neck is compressed or irritated at the point where it leaves the spinal cord. This can result in pain in shoulders, and muscle weakness and numbness that travels down the arm into the hand." *Radiculopathy (Nerve Root Disorder)*, Penn Medicine, https://www.pennmedicine.org/for-patients-and-visitors/patient-information/conditions-treated-a-to-z/radiculopathy (last visited Dec. 4, 2024).

[6] "Polymyalgia rheumatica (PMR) is the most common inflammatory rheumatic disease affecting people older than 50 years . . . . Common symptoms include pain and morning stiffness in the shoulder and pelvic girdle . . . . Fatigue, fever, and weight loss may also be present . . . . Diagnosis is made based on clinical history and the presence of elevated inflammatory markers." *Wilkinson v. Sec'y of Health & Hum. Servs.*, No. 18-1829V, 2024 WL 3857696, at *1 (Fed. Cl. Spec. Mstr. July 22, 2024) (citing Ingrid E. Lundberg, *An Update on Polymyalgia Rheumatica*, 292 J. Internal Med. 717 (2022)) (cleaned up).

medical literature, and on January 25, 2024, the Chief Special Master held a hearing where the parties' experts testified. Dec. at 1, 3, 7–8.

1. Petitioner's Evidence and Expert's Testimony

Petitioner's expert, rheumatologist Dr. Petros Efthimiou, M.D., provided two reports and testified at the hearing. *Id*. at 3–7. He "acknowledged that he does not have specific expertise in immunology" even though "much of the opinion he offered . . . involves immunologic issues." *Id.* at 3. Dr. Efthimiou proposed that PMR "could be caused by a Tdap vaccine." *Id.*

Although "[he] acknowledged that PMR's etiology was not fully understood," Dr. Efthimiou testified that PMR "was likely autoimmune (and more specifically an autoinflammatory condition)." *Id.* at 3–4. He explained a theory of how PMR disease develops: an initial innate response to a foreign antigen—described as a nonspecific, powerful inflammatory response—is followed by an adaptive immune response that leads antibodies and T cells to attack the foreign antigen. *Id.* at 4. Dr. Efthimiou referenced scientific articles filed by Respondent that he claimed show that PMR occurs in a context of elevated cytokines (immune cells stimulated during the innate response) and T helper cells that encourage the production of antibodies specific to a foreign antigen. *Id.*

To link this theory to vaccination, Dr. Efthimiou proposed that "some kind of environmental trigger," including certain viruses, "could reasonably explain PMR in many cases." *Id.* He then reasoned that vaccinations could provoke the same kind of immune response in three specific ways. First, a vaccine could impact helper T cells that influence antibody production. *Id.* Second, a vaccine antigen could prompt a response from autoreactive T memory cells that had "previously been exposed to a particular antigen." *Id.* In the context of Petitioner's case, he hypothesized that if an individual had been exposed before to the "tetanus toxoid vaccine component," T memory cells with prior exposure could recognize the antigen and prompt a response. *Id.* Finally, Dr. Efthimiou averred that the inflammation at first instigated by the vaccine might later overwhelm immune regulatory cells and encourage disease development. *Id.* Dr. Efthimiou denied that this theory involved "three seemingly separate immunological mechanisms" and emphasized that the theory stemmed from the initial stimuli experienced at the outset of vaccination. *Id.* at 4–5.

Dr. Efthimiou's theory relied on additional assumptions. First, he "devoted a substantial part of his testimony" to explaining that disease progression depended on "a person's individual susceptibility to a damaging autoimmune process." *Id.* at 5. He proposed that several genetic mutations contributed to disease and argued that PMR was "likely associated with certain subtypes of human leukocyte antigens ('HLA')." *Id.* He claimed that "someone possessing a mutated HLA gene was more likely to experience an autoimmune disease, under the right circumstances." *Id.* Petitioner's expert admitted that "[m]erely possessing a specific HLA mutation did not guarantee" PMR, and "an environmental trigger was still required." *Id.* And Dr. Efthimiou ultimately "admitted that there was no evidence Petitioner possessed a genetic susceptibility that could be associated with PMR." *Id.* at 7.

Dr. Efthimiou also relied on a theory of immune system "senescence." *Id.* at 5. He asserted that a break in immune tolerance occurs as one ages, leading to the possibility of

increased autoimmune disease because the body is less effective at fighting foreign pathogens. *Id.* at 4. He thus reasoned that Mr. Munoz's age "likely made him even more prone" to a vaccine-caused form of PMR. *Id.* at 5. Yet Dr. Efthimiou acknowledged on cross-examination that clinical studies on the Tdap vaccine's impact on older patients have found the opposite was true: "immune response [was] lower (and hence less effective)." *Id.* Finally, Dr. Efthimiou "allowed that his contentions about immunologic senescence did not have scientific or medical support specific to the impayct [sic] of vaccines in encouraging the development of PMR." *Id.* at 7.

Dr. Efthimiou also relied on studies filed in this case, including a study authored by Paolo Falsetti and others (the "Falsetti study"). *Id.* at 5 (citing Ex. 58, ECF No. 43-1). This study determined six out of fifty-eight patients had received a vaccine prior to PMR symptoms. *Id.* However, Dr. Efthimiou "acknowledged that [the study's] authors had relied on self-reporting by existing PMR patients . . . to determine . . . that (in the subjective view of the surveyed patients) there might have been a relationship between the two." *Id.* at 5–6. And he admitted that its authors "did not reach a scientifically-reliable conclusion," as it would have been "'impossible' for such a small sample." *Id.* at 6 (citing Tr. at 118).

Petitioner's expert also highlighted an article published by Alessandra Soriano ("Soriano article"). *Id.* (citing Ex. 34, ECF No. 24-11). This article reviewed case reports involving the flu vaccine. *Id.* The article referenced a case report, the underlying details of which were not filed in this case. *Id.* This lone report involved an observed temporal association between a tetanus vaccine—which would contain comparable antigens to a Tdap vaccine—and PMR in a woman in her sixties. *Id.* However, the Soriano article described that this woman suffered a *relapse* of PMR—not a new onset as Mr. Munoz had. *Id.* *See also* Ex. 34 at 3. And Dr. Efthimiou "admitted nothing [else] was known about this individual relevant to the case (such as whether she had previously received a Tdap vaccine, what had possibly caused her PMR the first time, or anything about her treatment or disease severity)." Dec. at 6 (citing Tr. at 119–21). Further, the expert "admitted he could offer no literature generally evaluating a purported PMR-Tdap connection" other than these case reports. *Id.* at 7.

As for the autoreactive or helper T cell component of the theory, Petitioner's expert "deemed it likely Mr. Munoz had been exposed to the vaccine before." *Id.* at 6–7. But he "admitted he had no evidence of this, and was therefore engaging in some speculation." *Id.* at 7. Dr. Efthimiou also speculated that co-administration of the pneumococcal vaccine with the Tdap could have contributed to the injury, but "admitted he had offered nothing specific to" a co-administration theory. *Id.* at 6 n.8 (citing Tr. at 98, 99–101, 134).

2. Respondent's Experts

a. Dr. Roland Staud, M.D.

Dr. Staud, a rheumatologist, testified and filed a report. *Id.* at 7. He admitted Petitioner's PMR diagnosis was correct but "maintained its causes remain unknown." *Id.* PMR "*may* have some association with infection and environmental agents," he admitted. *Id.* (emphasis in original). That said, he asserted that the infections identified as possibilities "have no congruence with the Tdap vaccine's components." *Id.* (citation omitted). Dr. Staud

acknowledged case reports linking the flu vaccine to PMR but pointed to a dearth of reports on Tdap. *Id.* at 7–8. He denied any link between the Tdap or pneumococcal vaccines—or any vaccine, for that matter—and PMR. *Id.* at 8. He pointed to studies to support this assertion, including one finding no link for the pneumococcal vaccine. *Id.* To contest a tetanus or Tdap link to PMR, Dr. Staud noted that rheumatology organizations specifically recommend tetanus vaccination to individuals experiencing autoimmune inflammatory conditions like PMR. *Id.* And he asserted the Falsetti study's reliance on self-reporting and mere temporal associations undermined its conclusions. *Id.*

b. William Hawse, Ph.D.

Immunologist Dr. Hawse also submitted a report and testified. *Id.* He disputed Dr. Efthimiou's theory of an immunologic mechanism. While vaccines are intended to generate an immune response to specific antigens, Dr. Hawse stressed that response is not identical across different vaccines. *Id.* He disputed the proposition that vaccines could initiate an autoimmune disease tolerance. *Id.* Dr. Hawse also rejected Petitioner's senescence theory, reasoning that senescence involved the body generating "weaker responses to vaccination—not experiencing greater aberrant reactions with aging." *Id.* at 9 (citing to pre-market testing of the Tdap vaccine). He also challenged Dr. Efthimiou's proposal that a certain T cell lymphocyte could be "stimulated into a cascade, resulting in (or at least encouraging) PMR." *Id.* Dr. Hawse disputed the reliability of this proposition, and stated he did not know of any evidence showing the Tdap vaccine could promote production of this T cell or any others allegedly involved with PMR. *Id.* He also argued that literature supporting this conclusion "relied on artificial lab conditions . . . that could not be compared to the body's likely reaction to a vaccination." *Id.*

C. The Chief Special Master's Decision

On August 12, 2024, Chief Special Master Corcoran issued a Decision denying entitlement. Dec. at 1. He explained that "PMR has not generally been viewed in prior reasoned Program decisions as an injury likely caused by . . . Tdap—and nothing offered *in this case* suggests a basis for departing from these prior determinations." *Id.* at 1–2 (emphasis in original). He considered the medical literature, prior special masters' decisions regarding PMR, and the parties' experts' reports and testimony. *Id.* at 3–9, 15–17.

The Chief Special Master determined Petitioner failed to carry his burden of proof to preponderantly establish the first of the *Althen* prongs to demonstrate causation. *Id.* at 17. There was not "sufficient probative evidence allowing for the conclusion that it is more likely than not that a Tdap vaccine's components can trigger PMR." *Id.* at 18. He found that Petitioner's expert repeated arguments "that other special masters have routinely rejected as unpersuasive"; "fail[ed] to identify a specific antigen associated with the development of PMR"; did "not otherwise offer[] any more recent scientific or medical studies"; and made "too many speculative assumptions" and "large leaps" of logic. *Id.* at 17–18. And Respondent's experts "effectively and persuasively" highlighted both a lack of direct evidence and logical issues with Petitioner's theory. *Id.* at 17.

Since Petitioner failed on the first *Althen* prong, the Chief Special Master did not proceed to the second and third prongs. *Id.* ("[T]he failure to establish even one of the three *Althen*

prongs in the context of a causation-in-fact claim is sufficient basis for a claim's dismissal.") (citing *Dobrydnev v. Sec'y of Health & Hum. Servs.*, 566 Fed. App'x 976, 980 (Fed. Cir. 2014)).

D. Motion for Review

On September 11, 2024, Petitioner filed a motion for review of Chief Special Master Corcoran's Decision denying entitlement. Mot. at 1. Mr. Munoz asserts "legal error," claiming that the Chief Special Master "applied an incorrect evidentiary standard of review" under *Althen*'s first prong. *Id*. at 5. He asks that the Court set aside the Chief Special Master's conclusions as "clear legal error" and grant entitlement. *Id*. at 18. In the alternative, he requests the Court remand to the Chief Special Master with instructions on the proper legal standard. *Id.* Respondent filed its opposition to the motion on October 11, 2024. The case is ripe for resolution.

II. Standard of Review

Under the Vaccine Act, parties may request the United States Court of Federal Claims to review a special master's decision. 42 U.S.C. § 300aa–12(e)(1). Upon such review, the Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). *Accord* Vaccine Rule 27.

The standards in section 12(e)(2)(B) "vary in application as well as degree of deference" as each "standard applies to a different aspect of the judgment." *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). "Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Id.* "Thus, the [Court of Federal Claims] judge reviews the special master's decision essentially for legal error or factual arbitrariness." *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1574 (Fed. Cir. 1993). The standard of review is "the most deferential possible." *Munn*, 970 F.2d at 870.

When reviewing a special master's factual findings, the Court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *see also Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (stating that the Vaccine Act "makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters[']fact-intensive conclusions"); *Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009) ("[T]he law is settled that

neither the Court of Federal Claims nor the Federal Circuit can substitute its judgment for that of the special master merely because it might have reached a different conclusion.").

"[S]pecial masters have broad discretion to weigh evidence and make factual determinations." *Dougherty v. Sec'y of Health & Hum. Servs.*, 141 Fed. Cl. 223, 229 (2018). The special master does not need to "discuss every item of evidence in the record" when making a factual finding "so long as the decision makes clear that the special master fully considered a party's position and arguments on point." *Snyder v. Sec'y of Health & Hum. Servs.*, 36 Fed. Cl. 461, 466 (1996), *aff'd*, 117 F.3d 545 (Fed. Cir. 1997) (citation omitted); *see, e.g.*, *Hazlehurst v. Sec'y of Health & Hum. Servs.*, 604 F.3d 1343, 1352 (Fed. Cir. 2010) (noting that a reviewing court presumes that the fact finder has considered all the material in the record, whether or not it is mentioned in his or her decision). Furthermore, the "special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010). The Federal Circuit has made clear that the special master's credibility findings "are virtually unchallengeable on appeal." *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000).

III. Discussion

To receive compensation under the National Vaccine Injury Compensation Program, a petitioner must prove by a preponderance of the evidence that a vaccine caused the injury at issue. 42 U.S.C. §§ 300aa–11(c)(1), 13(a)(1). If the claimed injury is not listed in the Vaccine Injury Table (i.e., an "off-Table injury"), the petitioner may seek compensation by proving causation in fact. *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); 42 U.S.C. § 300aa–11(c)(1)(C)(ii). Here, it is undisputed that Petitioner suffered an off-Table injury, PMR, following his July 2, 2019 vaccination. Therefore, Mr. Munoz needs to prove "causation in fact" under the *Althen* test. *Althen*, 418 F.3d at 1278. To succeed under the test, a Petitioner must demonstrate by a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.*

Petitioner argues the Chief Special Master applied an incorrect legal standard for prong one. Mot. at 2–5. First, Mr. Munoz claims that the Chief Special Master erred in "reject[ing] the contention that [prong one] can be satisfied merely by establishing the proposed causal theory's scientific or medical plausibility." Mot. at 3. *See also* Dec. at 11. Second, the Chief Special Master imposed an elevated "requirement . . . [to] present a persuasive medical theory." Mot. at 4. Third, the Chief Special Master's application of this allegedly incorrect standard led him to conclude that Petitioner's evidence was insufficiently probative, which impermissibly raised the burden of proof. Mot. at 5. In response, the Government argues Petitioner misreads the controlling legal standard and asserts the Chief Special Master properly applied the Vaccine Act's preponderance standard to the evidence. Resp. at 5, 9, 15–18. For the reasons explained below, the Government is correct.

A. The Chief Special Master Articulated the Correct Evidentiary Standard for *Althen* Prong One.

Petitioner claims that he should have been able to "satisfy prong one by setting forth a biologically plausible theory" of causation. Mot. at 16–17 (cleaned up) (citing *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009)). Mr. Munoz incorrectly asserts that "'biological plausibility' remains the evidentiary standard for *Althen*'s first element." Mot. at 2–3 (citation omitted).

1. *Althen* Prong One Must be Proven by a Preponderance of the Evidence.

The standard of evidentiary proof under *Althen* prong one is preponderance of the evidence, not plausibility. The statute is clear on this point. *See* 42 U.S.C. § 300aa-13(a)(1)(A) ("Compensation shall be awarded . . . if . . . the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition."). The Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Sec'y of Health and Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. 2019) (citing *Moberly*, 592 at 1322). "Proof of a 'plausible' or 'possible' causal link between the vaccine and the injury . . . is not the statutory standard" and is too "relaxed." *Moberly*, 592 at 1322. "[S]imply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet [his] burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014). The Federal Circuit continues to affirm this proposition. *See, e.g.*, *Orloski v. Sec'y of Health & Hum. Servs.*, 839 F. App'x 538, 541 (Fed. Cir. 2021); *Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 23-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) ("[W]e have repeatedly explained that a petitioner must prove a medical theory by a preponderance of the evidence that a vaccination can cause a particular injury."). This is consistent with the frequent instruction that "[t]he petitioner's 'burden . . . to show [causation] by preponderant evidence'" applies equally to "each of the requirements set forth in" the *Althen* prongs. *Oliver v. Sec'y of Health & Hum. Servs.*, 900 F.3d 1357, 1361 (Fed. Cir. 2018). *See also Olson v. Sec'y of Health & Hum. Servs.*, 758 F. App'x 919, 922 (Fed. Cir. 2018).

Petitioner claims the Chief Special Master misread *Boatmon*. Mr. Munoz asserts that the Federal Circuit's rejection of plausibility does not apply to *Althen* prong one. Mot. at 3–4 (asserting "[t]he *Boatmon* court reserved a separate section to discuss *Althen* element one" that did not discuss plausibility and only used the terms "sound and reliable") (citing *J. v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 20, 43 (2021)). He is mistaken.

In *Boatmon*, the Federal Circuit reviewed the Special Master's finding that an expert's theory satisfied the first *Althen* prong despite being "only 'plausible.'" *Boatmon*, 941 F.3d at 1360 ("By the Special Master's and Dr. Miller's own assessment, Dr. Miller's theory is only 'plausible' . . . ."). The Federal Circuit reversed this finding. *Id.* "The [*Boatmon*] Special Master erred in allowing a theory that was at best 'plausible' to satisfy the Petitioners' burden of proof." *Id.* The Federal Circuit further rejected the plausible mechanism theory as "insufficient" under the first *Althen* prong. *Boatmon*, 941 F.3d at 1359–60. Further, the paragraph after *Boatmon*'s rejection of plausibility also reviewed and rejected the Special Master's finding explicitly under *Althen* prong one. *Id.* at 1360 (citing *Boatmon v. Sec'y of Health & Hum. Servs.*,

No. 13-611V, 2017 WL 3432329, at *21 (Fed. Cl. Spec. Mstr. July 10, 2017) (analyzing Petitioner's expert's evidence under "*Althen* Prong One")). *Boatmon* is clear that plausibility does not satisfy the first *Althen* prong.

2. Petitioner's Attempt to Refashion Plausibility as Preponderance is Unsupported by Precedent.

Petitioner admits that *Althen* prong one's standard is preponderance. *See* Mot. at 12. But he argues that "preponderant evidence of a *biologically plausible scientific explanation*" may satisfy the burden. *Id.* (emphasis added). *See also, e.g.*, *id.* at 10 (stating that Mr. Munoz must provide preponderant proof "to propound a biologically plausible theory"). But as Respondent points out, "grafting plausibility onto preponderance" would "make little, if any, sense" in light of the Federal Circuit's repeated rejection of plausibility as distinct from and impermissibly lower than preponderance. Resp. at 15, 15 n.8. *See also Kaladjzic*, 2024 WL 3064398, at *2 ("[A] less than preponderance standard . . . is plainly inconsistent with our precedent.") (citing *Moberly*, 592 F.3d at 1322); *K.A. v. Sec'y of Health & Hum. Servs.*, 164 Fed. Cl. 98, 125 (2022) (rejecting petitioner's "attempts to refashion the first *Althen* prong standard" as a plausibility test).

Petitioner relies on *Andreu*, which found "[t]he first [*Althen*] prong was satisfied because . . . the Andreus' expert[] presented a 'biologically plausible' theory." *Andreu*, 569 F.3d at 1376. But the Federal Circuit has directly rejected this interpretation. It stated that "in *Andreu*, although we noted at one point that the petitioner's expert presented a 'biologically plausible theory,' *Althen* prong one was not disputed, and we thus could not have endorsed a lower standard of proof than the preponderance standard." *Kalajdzic,* 2024 WL 3064398, at *2.

Similarly, other cases dealing with plausibility were ones where causation was conceded by the Government, or the Court merely used the term "plausible" to explain a petitioner did not have to meet a standard of scientific certainty. *See, e.g.*, *Paluck v. Sec'y of Health & Hum. Servs.*, 786 F.3d 1373, 1377, 1380 (2015) ("[T]he government does not meaningfully dispute that [petitioner's] theory of causation is medically plausible. Indeed, the government conceded that vaccination could have, in theory, exacerbated [petitioner's injury]."); *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072, 1085 (2020) (using term "plausible" to explain that a petitioner need not present "medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory" to prove a causation theory preponderantly). Thus, cases referencing plausibility at most stand for the unobjectionable proposition that *Althen* prong one "does not require medical certainty" but also "does not absolve Petitioner from his burden to present a 'persuasive' theory supported by 'reputable' scientific or medical evidence." *Trollinger v. Sec'y of Health & Hum. Servs.*, 167 Fed. Cl. 127, 138 (2023).

Similarly, Petitioner misreads *Kottenstette*. As this Court stated—and the Federal Circuit affirmed: "a special master need not require proof of a specific biological mechanism for *Althen* prong one." *Howard v. United States*, No. 16-1592V, 2023 WL 4117370, at *5 (Fed. Cl. May 18, 2023) (citing *Kottenstette v. Sec'y of Health & Hum. Servs.*, 861 F. App'x 433, 437 (Fed. Cir. 2021)). "*Kottenstette* did not dilute the preponderance standard . . . . The only references to plausibility throughout the decision are direct quotes from the decisions below. Its ruling made no mention of plausibility and, instead, hinged on whether 'sufficient evidence' weighed in favor of preponderance." *Id.* And the Federal Circuit in *Kaladjzic* affirmed that "*Kottenstette* . . .

[does not] undercut[] the requirement that a petitioner's medical theory must be proven by preponderant evidence." 2024 WL 3064398, at *2.

3. The Chief Special Master Identified the Correct Standard.

The Chief Special Master correctly explained Petitioner's burden to prove the first *Althen* prong by a preponderance of the evidence. Dec. at 10 ("[P]etitioners bear a 'preponderance of the evidence' burden of proof."), 11 (citing caselaw rejecting plausibility as to first *Althen* prong). He explained that the theory need "only be 'legally probable, not medically or scientifically certain.'" *Id.* at 10 (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). And he correctly stated that "[p]roof of medical certainty is not required" and "epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory" are not mandatory. *Id.* at 10 (citations omitted). *Cf. Kottenstette*, 861 F. App'x at 441. To the extent that he determined that Petitioner's evidence "somewhat allow[ed] for a *faint possibility* that a vaccine could impact" disease development, the Chief Special Master properly found this insufficient. Dec. at 18 (emphasis in original). *Cf. Moberly*, 592 F.3d at 1322. And as discussed further in III.C, the Chief Special Master applied the preponderance standard to determine Petitioner failed to provide "sufficient probative evidence allowing for the conclusion that it is more likely than not that a Tdap vaccine's components can trigger PMR." Dec. at 18.

B. The Chief Special Master Did Not Incorrectly Require an Impermissibly High "Persuasive Theory" Under *Althen* Prong One.

Next, Petitioner argues the Chief Special Master required him to present "a persuasive theory" under *Althen* prong one that impermissibly raised the evidentiary burden. Mot. at 5–6 ("The Chief's bottom line was that Mr. Munoz's medical theory was not bulwarked by sufficient probative scientific/medical evidence to allow him to conclude that *Althen*'s prong one was *persuasively* proven.") (emphasis in original). But the Chief Special Master did not err.

A special master's obligation to examine the evidence under the preponderance standard requires her to "inquir[e] into the soundness of scientific evidence" presented. *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing Vaccine Rules of the Court of Federal Claims Rule 8(b)(1)). Special masters are responsible for "[w]eighing the persuasiveness of particular evidence" by "assessing the reliability of testimony." *Moberly*, 592 F.3d at 1325. "The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories," and "[a]s such, the special master's credibility findings 'are virtually unchallengeable on appeal.'" *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1361).

First, Petitioner appears to misconstrue the Decision below. The Chief Special Master properly articulated Petitioner's burden to prove a "reputable medical theory" that is "based on a sound and reliable medical or scientific explanation" but need only be "legally probable, not medically or scientifically certain." Dec. at 10 (citation omitted). Second, contrary to the Petitioner's claims, the Decision's references to "persuasiveness" are almost entirely related to describing the quality of the evidence. *See, e.g.*, *id.* at 13 (explaining that oral or written testimony "may be more persuasive than written records"), 14 (explaining role of *Daubert* factors "with respect to [evaluating] persuasiveness of expert testimony"), 15 (stating a decision

"may be 'based on the credibility of the experts and the relative persuasiveness of their competing theories'"), 16 (describing past special masters' decisions as persuasive guidance), 17 (rejecting a specific causation opinion as "unpersuasive" and describing Respondent's experts as "effectively and persuasively rebutt[ing] Petitioner's causation contentions").

The Chief Special Master noted that a prior special master's decision analyzed the persuasiveness of a petitioner's causation theory. *Id.* at 16. He also parenthetically cited a case which used the term "reliable and persuasive causation theory." *Id.* at 17 (citing *Palattao v. Sec'y of Health & Hum. Servs.*, No. 13-591V, 2019 WL 989380, at *36 (Fed. Cl. Spec. Mstr. Feb. 4, 2019)). But the Chief Special Master cited that case for the principle that a petitioner must provide probative evidence of a causal theory that "applies to the circumstances at hand." *Id.* at 17. This is merely consistent with the edict that a petitioner "must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Broekelschen*, 618 F.3d at 1345.

Third, and most importantly, the Chief Special Master would not have erred in evaluating the persuasiveness of the evidence or the theory because the Vaccine Act places a "statutory burden of persuasion . . . upon the petitioner [by] 42 U.S.C. §300aa-13(a)(1)" to prove causation in off-table injuries. *Hodges*, 9 F.3d at 961. Thus, the Federal Circuit has made clear that the preponderance standard is one of persuasion:

> The petitioner is not required to prove the case to a level of scientific certainty. Rather, the burden of showing something by a preponderance of the evidence, the most common standard in the civil law, simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence.

LaLonde, 746 F.3d at 1338. *See also Moberly*, 592 F.3d at 1322 (citing *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.,* 508 U.S. 602, 622 (1993)).

Accordingly, *Althen* held petitioners must "prove by a preponderance of the evidence that the . . . vaccination caused" the injury with a "persuasive medical theory." *Althen*, 418 F.3d at 1278. *See also Oliver*, 900 F.3d at 1361 ("The Chief Special Master thoroughly evaluated both parties' evidence as to each *Althen* prong and found the Government's more persuasive."); *Cedillo*, 617 F.3d at 1349 (affirming special master's finding that the "fatal deficiency in the petitioner's causation theories [is] the lack of any persuasive evidence that the . . . vaccine can contribute to the causation"). This is why a special master's decision may be "based on the credibility of experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347.

As discussed in part III.C below, "[t]he Chief Special Master . . . took issue with the quality and quantity of [evidence], finding the overall support for [Mr. Munoz's] general causation theory unpersuasive and insufficient to carry [his] burden." *Bechel v. Sec'y of Health & Hum. Servs.*, 168 Fed. Cl. 602, 622 (2023). In using the term "persuasive," it is clear the Chief Special Master did not articulate a heightened standard. He merely "evaluated the evidence presented and found it lacking." *Howard*, 2023 WL 4117370, at *5. His use of the term "persuasive" is consistent with the Vaccine Act's preponderance standard, not a deviation from it.

C. The Chief Special Master Correctly Applied the Preponderance Standard to Find Petitioner Did Not Prove a Sound and Reliable Theory by Preponderant Evidence.

To meet the burden of preponderantly proving that the vaccine "can cause" the injury under *Althen* prong one, a petitioner must provide evidence of a "reputable medical or scientific explanation." *Boatmon*, 941 F.3d at 1359. The theory must be "sound and reliable," but need not prove causation to medical or scientific certainty. *Knudsen*, 35 F.3d at 548. Petitioners may use "circumstantial evidence" to meet their burden of proof. *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). "Proof of causation does not require identification and proof of specific biological mechanisms." *Kottenstette*, 861 F. App'x at 441 (internal quotations omitted). Nor is "[p]roof in the form of epidemiological studies or well-established medical evidence . . . mandatory." *Moberly*, 592 F.3d at 1325. The Chief Special Master applied this standard faithfully to the evidence.

"The Chief Special Master did not treat the presence or absence of specific kinds of evidence—such as medical and scientific literature—in Petitioner's filings as dispositive." *Trollinger*, 167 Fed. Cl. at 138. He acknowledged that Petitioner had provided some probative evidence. Dec. at 17. He credited Dr. Efthimiou's "insights" on PMR's pathogenesis, recognized a "faint possibility" that vaccines could impact immune response in relation to PMR, and lent some weight to Petitioner's theories on senescence and individual susceptibility. *Id.* at 18 (emphasis removed).

However, he ultimately determined Petitioner's theory contained analytical gaps, assumptions, and logical leaps that undermined its persuasive value. *See, e.g.*, *id.* at 17 (finding Petitioner did not "provid[e] sufficient preponderant proof that the Tdap vaccine could likely initiate such a complex, interconnected disease process"), ("[Dr. Efthimiou] fails to identify a specific antigen associated with the development of PMR."), 17–18 ("Petitioner assumes different susceptibilities . . . that are not bulwarked with enough evidence to show that vaccination likely poses risks in these contexts."), 18 ("[T]he aspects of Dr. Efthimiou's theory relying on immune system senescence were ultimately not well constructed or substantiated."), ("[T]here are too many speculative assumptions [in Petitioner's case]."). And Petitioner's expert admitted many "evidentiary holes in his theory" that required him to "engag[e] in some speculation" as to nearly every portion of his theory. *Id.* at 7. *See also id.* at 6, 7. These admissions, for the Chief Special Master, further undercut the reliability of Petitioner's evidence. *See e.g.*, *id.* at 17 (noting Dr. Efthimiou "even admitted during testimony that there were not even case reports . . . other than the unfiled [Soriano] report).

Given these evidentiary gaps, the Chief Special Master was within his discretion to conclude there was "too great an analytical gap between the data and the opinion proffered." *Cedillo*, 617 F.3d at 1339 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). Given his determination that Petitioner's complex theory "relied on the vaccine doing multiple things" and "affect[ing] the immune process at so many different inflection points," the Chief Special Master reasonably found the evidence Petitioner put forward insufficient "to connect all the dots." Dec. at 17.

Petitioner also claims the Chief Special Master "require[d] [him] to provide specific pathologic mechanisms" or "objective proof." Mot. at 10 (emphasis removed). But the Chief

Special Master did not require Petitioner to propose a specific mechanism: he merely discounted the persuasiveness of the one proposed. Mr. Munoz protests that the information in the Falsetti study and Soriano article, which purportedly identified an association between the tetanus toxoid and PMR, should have been given more weight. *See, e.g.*, Mot. at 8, 12–15. Petitioner also objects to the Chief Special Master's statement that case reports generally "stand as weak evidence to support causation." Dec. at 18.

While case reports have "reduce[d] . . . evidentiary value" compared to formal epidemiological studies, the Chief Special Master did not dismiss the Falsetti study or Soriano article out of hand. *Echols v. Sec'y of Health & Hum. Servs.*, 165 Fed. Cl. 9, 17 (2023) (cleaned up) (quoting *Campbell v. Sec'y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011), *aff'd,* 786 F.3d 1373 (Fed. Cir. 2015)). The Chief Special Master fully considered and analyzed the Falsetti study. He acknowledged that it "underscored Dr. Efthimiou's prior arguments about senescence" and that some of its data were "consistent with Petitioner's medical history." Dec. at 5. But the Chief Special Master found the study lacked reliability because of its reliance on patients' self-reporting of causation, its absence of a scientifically-reliable conclusion, and its finding of at most only a "possible" temporal relationship. *Id.* at 6, 8. The Chief Special Master also cited a prior special master's decision that considered the Falsetti material and found it unpersuasive. Dec. at 16 (citing *Dycke v. Sec'y of Health & Hum. Servs.*, No. 18-106V, 2023 WL 4310701, at *24 (Fed. Cl. Spec. Mstr. June 7, 2023)).

The decision similarly evaluated the Soriano article and its second-hand case summary regarding an observed tetanus-PMR association. Dec. at 6, 17. However, the Chief Special Master identified multiple reasons to discount Petitioner's reliance on this case report. These included the article's lack of analogous circumstances and applicable details. The subject in question had "experienced a *relapse* of PMR." *Id.* at 6 (emphasis in original). In contrast, Mr. Munoz experienced a new onset. *Id.* And the Chief Special Master noted Dr. Efthimiou's admission of the lack of any other relevant information about this individual. *Id.* at 6. He observed that the case report was "inapplicable to this case as well, since it is not known that Mr. Munoz did previously receive a Tdap vaccine or experience a reaction to it." *Id.* at 6 n.7. And he found the fact that there were no other case reports connecting PMR and tetanus outside this sole "unfiled report" further reduced the Soriano article's persuasiveness. *Id.* at 17.

The Chief Special Master also reasonably found Petitioner's theory on genetic susceptibility—a critical element of his immunologic theory—lacking because it required similar logical leaps. *Id*. at 5. Although Petitioner "offered some evidence explaining how individual susceptibility might also encourage PMR," the Chief Special Master determined there was a dearth of evidence to support its application to Petitioner's specific case. *Id.* at 18. Petitioner's expert also acknowledged this weakness. *Id.* at 7 ("Dr. Efthimiou admitted that there was no evidence Petitioner possessed a genetic susceptibility that could be associated with PMR."). Mr. Munoz had the burden to provide a "reputable medical or scientific explanation that pertains specifically to [his] case." *Broekelschen*, 618 F.3d at 1345. The Chief Special Master found Mr. Munoz did not meet his burden. The theory relied on "speculative assumptions about . . . [his] unspecified genetic susceptibilities," and "assumed, in circular fashion" that Petitioner possessed a mutated HLA gene "merely because Petitioner developed PMR." *Id.* at 18. Thus, the Chief Special Master did not require "proof of causation to the level of scientific certainty." *Boatmon*, 941 F.3d at 1360 (quoting *Moberly*, 592 F.3d at 1324). Instead, he assessed the evidence for "indicia of reliability to support the assertion of the expert witness" and found it lacking. *Id.*

The Decision's assessment of Dr. Efthimiou's senescence theory was similar. Dr. Efthimiou testified that aging would generate "more autoimmune disease potentiality." Dec. at 5. However, he also acknowledged that clinical studies generally found immune responses to be lower with age because the body "generat[es] weaker responses to vaccination," a point emphasized by Dr. Hawse. Dec. at 5, 9 (internal quotes omitted). The Chief Special Master found Dr. Efthimiou's senescence theory illogical "since the very concept of immune response senescence involves *reduced* immune system effectiveness, rather than greater aberrance due to age." *Id*. at 18 (emphasis in original). As a result, he found this theory "ultimately not well constructed or substantiated." *Id.*

Petitioner also claims in a footnote that "the Chief's decision . . . fails to accurately note the factual receipt of two covered vaccinations concomitantly." Mot. at 2 n.1. This is inaccurate. He addressed this fact. *See, e.g.*, Dec. at 6–7 n.8 ("Dr. Efthimiou made some references to the possibility that the other vaccine Petitioner received at the relevant time—the pneumococcal vaccine—could have contributed to his injury."). The Chief Special Master found Dr. Efthimiou's testimony inconclusive. *Id.* ("[Dr. Efthimiou] ultimately seemed to posit only that it was 'highly possible' a combination of vaccines played a contributory causal role."). Further, Petitioner's expert "admitted he had offered nothing specific to an association between PMR and co-administration of these two vaccines." *Id.* (citing Tr. at 134). The Chief Special Master also found "most of Petitioner's evidence goes to the Tdap vaccine's role" rather than a co-administration theory. *Id.* He also noted that Dr. Efthimiou "admitted in passing he could offer less evidence on this topic" than the Tdap theory. *Id.* Thus, the Chief Special Master found the co-administration theory "facially less-supported" than the Tdap theory, and Dr. Efthimiou's testimony on co-administration of "even less persuasive value." *Id*. There is no basis for the Court to reverse this finding.

In summary, Petitioner's Motion requests this Court "review the evidence anew to conclude that [Mr. Munoz] has presented preponderant evidence linking the tetanus containing vaccines specifically to PMR illness." Mot. at 17. But the Court may "not reweigh the factual evidence," *Porter*, 663 F.3d at 1249, or "second guess the [Chief] Special Master's fact-intensive conclusions." *Hodges*, 9 F.3d at 961. The Chief Special Master's Decision "grappled with the quality and quantity of the evidence . . . and found both metrics lacking." *Howard*, 2023 WL 4117370, at *6. His findings were not in error.

IV. Conclusion

The Chief Special Master applied the correct legal standard and weighed the evidence properly within his discretion. Accordingly, the Court **DENIES** Petitioner's Motion for Review and **SUSTAINS** the Special Master's Decision. The Clerk of the Court shall enter judgment for Respondent accordingly.

IT IS SO ORDERED.

s/ Carolyn N. Lerner
CAROLYN N. LERNER
Judge